K001708

MAR - 1 2001

Marietta, Georgia
30066-6029 USA

510 (k) SUMMARY

Establishment

Registration Number: 1040777

Submitter:

Gerry Richardson
Respironics, Inc
1255 Kennestone Circle
Marietta, GA. 30066
Phone: 770-429-2853
Fax: 770-499-1139

Date Prepared: May 13, 2000

Name of Contact: Gerry Richardson, Director of Engineering

Common Name: Pulse oximetry display software

Device Model Number: 920M-41

Device Classification: Oximeter, 21 CFR 870.2700, code 74 DQA

Predicate Devices: Nellcor Puritan Bennett, Inc. Score Software.
Originally cleared under K961450 (08/01/96)

Device Description: PROFOX SOFTWARE is an accessory to the Respironics model 920M Pulse Oximeter.

The purpose of PROFOX SOFTWARE is to download stored oximetry data from the Respironics 920M pulse oximeter, allow users to edit data, store tests and print a variety of reports.

The software will operate under Windows 95, Windows 98 or Windows NT with service pack 3.0 or greater.

The software will report SpO2 values between 1 and 100, and pulse rate values from 25 to 250, which is the range of the pulse oximeter.

Of the six reports, some features are optional to better suit individual practice and needs. Any saved test can be converted into ASCII format for importing to spreadsheets or databases. The patient information may consist of the patient name, an ID number, name of requesting physician and comments. In addition to the SpO2 and pulse data, the date and time of the study, the duration of

the study, and the sampling resolution is stored. The oximetry data may be edited to remove undesired segments.

Intended Use: PROFOX SOFTWARE is an accessory to the Respironics model 920M Pulse Oximeter. It is intended to provide the Health Care Professional with the ability to collect, view, analyze, report and edit information recorded by the 920M Pulse Oximeter.

Comparison of Technological Characteristics: The predecessor to PROFOX SOFTWARE is SCORE SOFTWARE manufactured by Nellcor Puritan Bennett.

PROFOX SOFTWARE is used to acquire pulse oximetry data from a pulse oximeter and allow the Health Care Professional to edit, store data, and print a variety of reports. The product operates under a windows operating system on a standard personal computer. These features are consistent with and comparable to the predicate device

Summary of Performance Testing: PROFOX SOFTWARE was tested to ensure that it was capable of meeting all its intended functional requirements.

PROFOX SOFTWARE is a computer controlled medical device and as such was tested and documented consistent with the requirements outlined in "*Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510 (k) Review*" published by the Office of Device Evaluation within the CDRH. PROFOX SOFTWARE passed all tests.

Conclusions: The cumulative test results demonstrated the functionality, safety, and effectiveness of PROFOX SOFTWARE, as well as its substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2001

Mr. Gerry Richardson
Respironics Georgia, Inc.
175 Chastain Meadows Court
Kennesaw, GA 30144-3724

Re: K001708
Profox Software, Model 920M-41
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: December 12, 2000
Received: December 19, 2000

Dear Mr. Richardson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

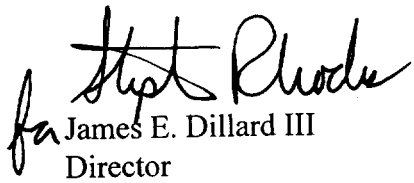
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K001708

Device Name: PROFOX SOFTWARE

Indications for Use:

PROFOX SOFTWARE is an accessory to the Respironics model 920M Pulse Oximeter. It is intended to provide the Health Care Professional with the ability to collect, view, analyze, report and edit information recorded by the 920M Pulse Oximeter.

PROFOX SOFTWARE does not operate coincidently with the pulse oximeter, but rather is used to download the pulse oximeter after the completion of the study.

PROFOX SOFTWARE does not have any utility for "real time" viewing of pulse oximetry signals.

PROFOX SOFTWARE is not intended nor has any utility to be used as a monitoring device.

PROFOX SOFTWARE is to be used by and under the control of a Health Care Professional.

Stephen Rhodes
Christy Foreman
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001708

X PRESCRIPTION USE or ___ OVER-THE-COUNTER USE

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation